



K963355

August 18, 1996

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To whom it may concern:

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Trade Name - SoloPak Medical Products, Paragon Infusion Pump and Administration Sets

Common Name - Infusor, Infusion Pump, and Administration Sets

Classification Name - Infusion Pump and Intravascular Administration Set

The SoloPak Medical Products, Paragon Infusion Pump and Administration Sets are intended to be used as a system for the purpose of delivering drugs and solutions through an in-dwelling catheter. When a filled fluid container of the administration set is placed into the bottom shell and the two shells are threaded together, internal pressure is generated on the administration set drug container. This internal pressure and the flow restrictor in the distal end of the Paragon Administration Set provide components that control the flow of fluid from the administration set. This system has been tested and has demonstrated it can consistently deliver within + or - 10% of the labeled flow rate.

The pump is made of two cylindrical high impact plastic shells with a pressure plate assembly in the top shell. It is packaged individually and can be cleaned after each use and reused. The Administration Sets that function with the pump consists of a 110mL PVC drug container, PVC tubing, a fill valve, PVC tubing, an on/off clamp, a 1.2 Micron Filter, a male Luer lock adapter with an integrated flow restrictor and tip protectors. The administration Sets are individually packaged as single use devices in tyvek and mylar pouches. They are EtO sterilized per AAMI guidelines and meet the requirements of the Federal Register Vol. 43, No. 122, June 23, 1978, pp 27482-3 for ethylene oxide residuals.

This pump and administration set system are substantially equivalent to the Sidekick Plus Infusion Pump and Administration Sets legally marketed by I-Flow Corporation under K#923875. Substantial equivalence can be claimed by SoloPak Medical Products for the Paragon Infusion Pump and Administration Sets because the components and the processes used to manufacture the Paragon Infusion Pump and Administration Sets are identical to those used in the predicate device. The same manufacturing site is used and the same designs employed in the manufacture of the pump and administration set. Based on these facts, the SoloPak Medical Products Paragon Pump and Administration Sets are substantially equivalent and are safe and effective when used as intended.

Sincerely,

A handwritten signature in black ink, appearing to read "Ron Haselhorst", written over a horizontal line.

Ron Haselhorst
Director of Regulatory Affairs\Quality Assurance